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Gang Wang
Tom Finn
Lori Tull

Liz Smith
Nicole Provost
Connie Spooner
Heidi Hagan

The FDA requested a telecon with the sponsor to schedule a 2nd inspection of their NJ facility in response to the BLA submission received 10/30/09. The FDA suggested that the 2nd or 3rd week of December would be a good target date for an inspection and asked whether Dendreon could be ready for an inspection at that time. Dendreon responded that it would be difficult for them to be ready at that time. One reason given was that they are in the process of hiring additional staff for that facility and they want to be at least training those new hires before the inspection. There is also scheduling issues to coordinate patients as part of their open label trial whose product will be made during inspection. The FDA asked if the week of January 11 would work. Dendreon responded that they could meet that date but it would be stressful. Dendreon proposed the last week of January. The FDA stated that there was concern about postponing an inspection that long because the FDA would like to give the sponsor sufficient time to resolve problems before the PDUFA due date. Dendreon responded that they intend to resolve any 483 issues within 10 business days of being issued a 483. A discussion followed about realistic time frames for responding to potential problems should they occur. The FDA and Dendreon came to agreement about Jan 25-29 as a tentative inspection date. Dendreon was willing to commit to that date, but the FDA wanted a few days to confirm that that time frame would work with FDA schedules.

A second item for discussion was the scale or throughput of manufacturing while on inspection. Dendreon proposed (b)(4) lots/day being processed while on inspection. The FDA agreed that in general that level of production would be adequate. The FDA proposed (b)(4) lots produced on one day, followed by continued manufacturing of those lots ----------(b)(4)----------. Dendreon agreed that a ----------(b)(4)---------- could be scheduled during inspection. The FDA also indicated that of the (b)(4) lots (b)(4) should be manufactured in -------(b)(4)---------- modules would be used. Dendreon asked for flexibility as to how many lots will be made in each module, for example, perhaps ----------(b)(4)----------. The FDA agreed that this would be acceptable.

Dendreon stated that they will provide a manufacturing schedule a week in advance that outlines what will be manufactured when. They will be processing actual product for the open access trial during that time period. Dendreon also indicated that most of the

manufacturing occurs at (b)(4) and that the inspection team may want to adjust their schedule accordingly.

Dendreon asked about the status of the EIR and will they be provided a copy. The FDA stated that the EIR from the previous inspection has been completed for some time but considers the file to still be open because the BLA was not approved and the 483 items have yet to be resolved. A second EIR will be generated after the 2nd inspection. Once that is completed Dendreon can request a copy of both reports. Dendreon indicated interest in getting a copy of the first EIR to make sure they have addressed all issues with the previous inspection. The FDA said they would look into whether Dendreon could formally request a copy.